K092106
p1/2

JAN 25 2010

Attachment 2

510(k) Summary

1. Submitter's Information

Name: TaiDoc Technology Corporation
Address: 6F, No.127, Wugong 2nd Rd., Wugu Township, Taipei County, Taiwan
Phone: 886-2-6625-8188
Fax: 886-2-6625-0288
Contact Person: Erica Li
Prepared Date: 06/22/2009

2. Name of Device

Trade Name: FORA P 20 Blood Pressure Monitor /U-RIGHT TD-3132 Blood Pressure Monitor
Common Name: blood pressure monitor
Classification Name: Noninvasive Blood Pressure Measurement System (per 21 CFR 870.1130)

3. Predicate Device

Trade/Proprietary Name:A&D Medical UA-851 THW Digital Blood Pressure Monitor
Common/Usual Name: blood pressure monitor
Manufacturer: A&D Engineering, Inc.
510 (k) Number: K082734

4. Device Description

The TD-3132 is an arm type blood pressure monitor. The device includes setting button, function button, LCD display, start/stop button, recall memory button, and arm cuff. The symbols displayed on LCD include month, date, hour, minute, systolic rate, diastolic rate, pulse rate, pulse symbol, blood pressure unit, battery display, error symbol, and memory record.

5. Intended Use

The intended use of TD-3132 is to measure human systolic, diastolic blood pressure and heart rate by using the oscillometric method. The measurement position of the device is the upper arm of the subject. This system should only be used for the testing on people over 18 years of age and over.

6. Comparison to Predicate Device

Both devices determine values of blood pressure by using oscillometric method. In this method, pulse waves are detected by using pressure sensors. Then the diastolic blood pressure, mean average pressure, and pulse pressure are derived. Furthermore, the systolic blood pressure and pulse rate are computed based on the information.

7. Non-clinical Performance

The results for non-clinical trials as presented in this document demonstrated the conformance to the SP10 standard that is also the reference standard for the predicate device. Therefore, the substantial equivalence between the devices is determined.

8. Clinical Performance

The clinical test results of the TD-3132 showed the functions of the device met the criteria in the SP10 standard. Hence, it is reasonable to conclude the substantial equivalence between the devices.

9. Conclusions

TD-3132 demonstrates satisfactory performance (safety and effectiveness) and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 25 2010

Taidoc Technology Corporation
c/o Ms. Erica Li
Management Representative
6F, No. 127, Wugong 2nd Rd Wugu Township
Taipei County
China (Taiwan) 24888

Re: K092106
Trade/Device Name: FOR A P20 Blood Pressure Monitor/U-RIGHT TD-3132 Blood Pressure Monitor
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: January 3, 2010
Received: January 8, 2010

Dear Ms. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092106

Attachment 1

Indications for Use Statement

Applicant: TaiDoc Technology Corporation

510(k) Number (if known): K092106

Device Name: FORA P20 Blood Pressure Monitor /U-RIGHT TD-3132 Blood Pressure Monitor

Indications for Use:

The FORA P20 Blood Pressure Monitor /U-RIGHT TD-3132 Blood Pressure Monitor is intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate by using a non-invasive technique in which an inflatable cuff is wrapped on the upper arm. This system should only be used for the testing on people over 18 years of age and over.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092106